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DATE: October 24, 2006 TELEFAX NO. 571-273-8505

TO: Examiner Michel Graffeo

FROM: Barry I. Hollander, Reg. 28,566

SUBJECT: Re: Application S.N. 09/782,320

Dear Mr. Graffeo:

Per our telephone conference today, October 24, 2006, attached is a copy of the earliest filed priority application, Provisional Application Serial No. 60/029,038 filed 10/28/1996.

If you have any questions, please do not hesitate to contact me at 703-383-4800. Best regards.

Barry I. Hollander

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Method for the embedding and encapsulation of components.

Description of the invention

The present invention relates to a continuous method that allows components, for example pharmaceutically or biologically or nutritionally active components, or drugs or other active components to be embedded or to be encapsulated in a concentration of about less than 1% to about 85% into a matrix, that comprises a substantial amount of carbohydrates.

The Method comprises:

Admixing of at least one starch containing solid such as native starch from corn, wheat, rice, potato, tapioka, or high amylose starch.or flours from grains such as corn, wheat, rice, barley, oat, rye and sufficient amount of water and optional additional ingredients, such as oil, fat, emulsifiers, dextrins, N-Vinylpyrrolidon-2-one (NVP) to substantially gelatinize the starch without substantially destructurizing and destrinizing it, i.e. cooking the starch at a low shear. An overall quantitative measure of the shear inside an extruder is the specific mechanical energy input that is according to this invention below about 150 Wh/kg, more preferably below about 100 Wh/kg and most preferably below about 50 Wh/kg. The amount of water necessary to obtain a low specific mechanical energy may be from about 35% to about 50%, preferably from about 35% to 45% , most preferably about 40% based on Starch by weight.

heating the mix above the gelatinization temperature of the starch while conveying and mixing it inside an extruder,

maintaining at least 100 degree Celsius , preferably between 120 and 150, for example 125 to 140 degree Celsius product temperature for sufficient time to substantially or preferably completely gelatinize the starch for at least about 4 l/d of extruder length.

maintaining a pressure in the cooking section between about 5 - 100 bars, preferably between about 15 and 35 bars.

decreasing the product temperature to substantially lower than 100 degree Celsius, for example between about 85 and 95 degree Celsius by means of either an open extruder barrel section, a vacuum dome/vent port and/or by decreasing the barrel temperature or a combination of the above,

removal of water through either venting or by using one or more open extruder barrel sections that are connected to a vacuum means as indicated in Figure 2.

conveying the gelatinized mass with reduced moisture and lower temperature towards a subsequent extruder barrel section, while maintaining sufficient temperature to admix the encapsulant without its thermal or mechanical destruction,

adding one or more active components that are either pharmaceutically, nutritionally or biologically active into a subsequent barrel section of the extruder , the added components may be also heat and/or shear sensitive and may be added , admixed and embedded into the carbohydrate based matrix without their thermal or mechanical destruction.

using , for the purpose of adding the components, a feeding apparatus commonly known as side feeder for solids, or liquid injection nozzles for liquids or a combination of both. If an injection nozzle is used, the pressure to inject the liquid encapsulant needs to be sufficiently high to inject the liquid into the extruder barrel, for example, if the pressure of the plastizised mass inside the extruder is 10 bars, the injection pressure needs to be about 2 to 5 bars higher , i.e. 12 to 15 bars. In the case that the encapsulant has a lipophilic nature, it may also be pretreated, such as coated, using for example waxy substances such as high melting fats or waxes with for example an emulsifier, such as glycerinmonostearate or the like in order to improve the homogeneity or to prevent separation between the lipophilic encapsulant and the hydrophobic matrix.

admixing the added ingredients using appropriate extrusion screw configuration as is described in Fig 2, 3a and 4. such as alternating small pitch conveying elements with distributive mixing elements, that are staggered and provide axially orientated leakage flow inside the extruder barrel, hence they cause the material flow to be continuously be disturbed without the mass to be sheared and thus cause the material to be mixed at low mechanical energy input. The total length of this distributive mixing section is about 3 to 10 l/d , preferably about 4 to 6 l/d to sufficiently admix and distribute and embed or encapsulate the added components into the matrix.

conveying the complete mix towards the extruder die using low pitch extruder screw conveying elements for the purpose to increase the degree of fill inside the extruder and thus to control the temperature profile of the mix inside the extruder barrel for the purpose of optimum viscosity adjustment and extrusion through the subsequent die openings.

extruding the mix through extrusion dies that have a diameter from about 0.5 mm to about 5 mm, preferably from about 1 to about 2 mm , the extruded rope having a crossectional diameter from about .5 mm to about 5 mm, preferably from about 1 mm to about 2 mm.

cutting the extruded rope at the die face using a rotating cutter. pelletizer or rotating knives. or cutting the rope away from the die using appropriate cutting means into pellets that have a l/d ratio of about 0.5 and 10, preferably about 1 .

means to vary the particle size by a) using variable speed cutter either at the end of the extruder or away from the extruder after the ropes have been conveyed for a short distance. for example between about 2 and 5 meters to allow further surface cooling, further surface drying and less stickiness to enable a better cutting of the ropes into pellets; and b) by having appropriate die diameter

varying the particle size to control the surface to volume ratio of the pellets to allow a controlled release of the encapsulant when the product it is being used as an agricultural agent with controlled release properties,

in case the product is being consumed by humans or animals, varying the particle size according to this invention is critical to a)control the surface to volume ratio of the pellets to allow a controlled release of the encapsulant during its pass through the mouth, the stomach and the intestine and b) to control the residance time of the pellets inside the stomach whereby particles smaller than 1 mm pass through faster than particles larger than for example 2.5 mm.

drying the pellets to sufficiently low moisture from less than about 12% to preferably less than about 10%. for example 6 to 9% by weight, most preferably to less than about 5 % to ensure sufficient storage stability of the pellets for example at least about 9 month , preferably at least about 18 month and most preferably at least about 36 month.

optionally applying filmbuilding substances onto pellets to further encapsulate and protect the extruded pellets. Filmbuilding substances are either based on native or modified starch. based on fat. based on protein. for example zein. based on shellac. based on chitosan. based on chitin or based on a combination of the above. Filmbuilding substances may contain additional components that protect the pellet from the influence of light , such as titaniumdioxide. cocoa based products or the like. or that protect the pellet from the influence of oxygen or air. Filmbuilding substances may be applied using spray nozzles that are located close to the die or after the drying means. when the moisture of the mass is at a level of sufficient storage stability as described above. Film building substances may be applied using commonly known fluid bed applications. or conventional coating methods as they are known in the industry.

removing volatile from surface, in case the filmbuilding substance application left volatiles onto pellet surface, using subsequent drying means.

The products that are made according to this invention might also be compressed in commonly used tablet presses to obtain compressed versions of the extruded pellets.

The final products have , according to the invention. following characteristics:

The starch component of the matrix is substantially or completely gelatinized and not substantially destructurized or dextinized.
The specific density of the pellets is between about 800 and 1500 g/liter
The particle size is uniform but can be controlled in a wide range. Practical ranges are between about 0.5 and 3 mm.
Products according to this invention are edible and intended for humans or animals.
In another embodiment, products according to this invention may contain encapsulated and/or embedded active components that either inhibit , promote , control or otherwise influence the growth of plants and/or their resistance against animals, diseases or weather and to control its ability to grow high yield . Example of such substances are herbicides, insecticides and nutrients.
Products are substantially not expanded. and have a transparent or translucent appearance. They are not foamy and not puffed.

According to the invention, the products contain a substantial amount of starches, optionally added fat to the matrix composition is less than 10%. preferably less than 5% for example from about 0% to about 3%. Fat acts as a plastizising agent and lowers the glass transition temperature of the final matrix which is subsequently lowering the storage stability of the product and thus unwanted.

according to the invention. the matrix may in addition contain sugars and starch hydrolysate products. i.e. dextrins of various molecular size . in order to modify the glass transition temperature of the final extrudate and thus to control the release of the encapsulants or embedded substances,

according to the invention. the matrix may in addition contain N-vinylpyrrolid-2-one (NVP) to modify the glass transition temperature of the final extrudate and to control the release of the encapsulants or embedded substances in gastric juice.

The key control parameter for the release of the encapsulam are the particle size of the pellet, the solubility of the gelatinized starch. the solubility of the added carbohydrates. the hydophobicity of the matrix and the character of an optional coating.

The particel size of pellets is controlled by extrusion forming and cutting process .

The solubility of gelatinized starch is controlled by cooking process. It is desired to obtain low mechanical energy input to minimize both destructurization and dextrinization of the starch. Starch, that has been dextrinized during extrusion might exhibit a negative effect on the stability of the pellets. whereas the amount and type of added dextrins may be used to control the glass transition temperature and release properties in aqueous or acid environment.
The hydrophobicity and the solubility in gastric juice environment of the starch based matrix may be adjusted by adding other hydrophobic and polymeric substances, combined with an emulsifier. Those substance may be advantageously added with an additional side feeder after the starch has been cooked.
Optional additional coatings can be used to enhance the effect of the embedding and to obtain a complete encapsulation, if nessecary.
Products according to the invention may also contain protein in their matrix , that exhibit glassy properties after extrusion cooking. such as zein. wheat gluten. soy protein. or other proteins form various other plant sources.

Examples of encapsulated substances may be from the group of pharmaceutically active components such as one or more of the following:
acetaminophen, acetohexamide, acetyldigoxin, acetylsalicylic acid, aclomycin, alprenil. benzocaine. beta-carotene. chloramphenicol, chlordiazepoxide. chlormadinone acetate. chlorothiazide. cinnarizine. clonazepam. codeine, dexamethasone, diazepam. dicoumarol, digitoxin, digoxin, dihydroergocamine, drotaverine, flunitrazepam. furosemide, gramicidin, griseofulvin. hexobarbital, hydrofluormethiazide, indomethacin, ketoprofen, lonetil. medazepam. mefruside, methandrostenolon e, methylprednisolone, methylsulfadiazine,

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nalidixic acid, nifedipine, nitrazepam, nitrofurantoin, nystatin, estradiol, papaverine, phenacetin, pheno-barbital, phenylbutazone, phenytoin, prednisone, reserpine, spironolactone, streptomycin, sulfamethazine, sulfamethizole, sulfamethoxazole, sulfamethoxydiazine, sulfaperin, sulfathiazole, sulfisoxazole, testosterone, tolazamide, tolbutamide, trimethoprim, thyrothricin.

Other components that might be suitable to be encapsulated and/or embedded are for example: bethamethasone, thioic acid, sotalol, salbutamol, norfenefrine, silymarin, dihuroergotamine, buflomedil, etofibrate, indometacin, oxazepam, beta acetyl digoxin, piroxicam, haloperidol, ISMN, amitriptylin, diclofenac, nifedipine, verapamil, pyritinol, nitrendipin, doxycycline, bromhexine, methylprdnisolone, clonidine, fenofibrate, allopurinol, pirenzepine, levothyroxin, tamoxifen, metildigoxin, o-(beta-hydroxyethyl)-rutoside, propicillin, aciclovir mononitrate, paracetamol, naftidrofuryl, pentoxifylline, propafenone, acebutolol, L-thyroxin, tramadol, bromocriptine, loperamide, ketotifen, fenoterol, cadobelisate, propanolol, enalaprilhydrogen maleate, bezafebrate, ISDN, gallopamil, xantinol nicotinate, digitoxin, flunitrazepam, benzyclane, dexapanthenol, pindolol, lorazepam, diltiazem, piracetam, phenoxymethylpenicillin, furosemide, bromazepam, flunarizin, erythromycin, metoclopramide, acemetacin, ranitidin, biperiden, metamizole, doxepin, diporassium chloroazepate, terazepam, esuramustine phosphat, terbutaline, captopril, maprotiline, prazosin, atenolol, glibenclamide, cefaclor, etilfrine, cimetidine, theophylline, hydromorphone, ibuprofen, primidone, clobazam, oxaceprol, medroxyprogesterone, flecainid, pyridoxal 5 phosphat glutaminate, hymechromone, etofylline clofibrate, vincamine, cinnarizine, diazepam , ketoprofen, flupentixol, molsimine, glibornuride, dimetinden, melperone, soquinolol, dihydrocodeine, clomethiazole, clemastine, glisoxepide, kallidinogenase, oxyfedrine, baclofen, carboxymethylcysteine, thioridazine, betahistine, L-tryptophan, mutrol, bromelaine, prenylamine, salazosulfapyridine, astemizol, sulpiride, benzerazide, dibenzepine, acetylsalicylic acid, miconazol, nystatin, ketoconazole, sodium picosulfate, colestyramine, gemfibrocil, rifampicin, fluocortolone, mexiletin, amoxicillin, terfenadrin, mucopolysaccharide polysulfade, triazolam, mianserin, naprofenic acid, amezinium metilsulfate, mefloquine, probucol, quinidine, carbamazepine, L-aspartate, penbutolol, piretanide, aescin amitriptyline, cyproterone, Sodium valproinate, mebeverine, bisacodyl, 5-aminosalicylic acid, dihydralazine, magaldrate, phenprocoumon, amantadine, naproxen, carteolol, famotidine, methyldopa, auranofine, estriol, nadolol, levomepromazine, doxorubicin, medofenoxate, azathioprine, flutamide, norfloxacin, fendiline, prajmalium bitartrate.

Other examples include substances from the group of the so called nutraceutical components, such as antioxidants, phytochemicals, hormons, vitamins, minerals, microorganisms, prebiotics, probiotics, trace elements, essential and/or highly unsaturated fatty acids.

Other examples may include products that constitute already an encapsulated product and need to be double encapsulated into an additional matrix according to the method and into shapes according to this invention

Patent References

Patent # EP 0 465 364 A1
Claimed is an antiobesity food and method to make it by extrusion of starches with Fatty Acids into an expanded product. The densities are between .1 and .3 g/cm^3.
Patent # EP 0 462 012 A2
Claimed is an antiobesity food and method to make it by extrusion of starches with Fatty Acids into an expanded product. Densities are between .1 and .3 g/cm^3.
Patent # US 3 962 416
Describes expanded product to contain at least one nutrient and one gelatinized starch

The product according to the current invention is not a food product, but an edible composition with the purpose to deliver encapsulated pharmaceutically or nutritionally active components. In another embodiment, the product is not a food and not an edible product, but applicable for agricultural means. The method of the current invention also differs substantially in that the pressure and temperature drop at the extruder die yield a product with different characteristics. The specific density of the products of the current invention is between about 0.8 to 1.3 g/cm^3
Products of the current inventions are not puffed, or expanded. They are rather in a granular form as to increase palatability and delivery to humans or animals in a substantially compact form, that is easy to swallow without

chewing. The substantially spherical shapes of the products of high density exhibit a substantially low ratio between surface area and volume and thus minimize or prevent surface related destructive reactions that occur upon the influence of oxygen, light and air , but also minimize the surface that would be available to expose the embedded material that is not encapsulated. Products of the current invention should , in case they are intended to be edible, not be substantially chewed , so that the pellets reach the digestive tract without substantial enzymatic hydrolysis in the mouth and furthermore to control their solution behaviour in gastric juice and furthermore to control the release of the embedded or encapsulated components either in the stomach and/or in the intestine.

Patent # WO 92/00130

The patent WO describes a continuous process to obtain an encapsulated biologically active product in a starchy matrix. It is specifically described, that biologically active agents and starch are being mixed before extrusion and being extruded as one blend. i.e. the encapsulant is being heated together with the starch. Alternatively , the core material to be encapsulated can be added and blended with the aqueous dispersion of starch after the starch and water have been subjected to an elevated temperature sufficient to gelatinize the starch. Additionally it is being specifically described that the extrusion process exposes the mix to high shear mechanical action at a temperature above the gelatinization temperature of the starch. The extrusion barrel temperatures described were between 58 and 98 degree Celsius. These temperatures are above the gelatinization temperatures of the starch, however, the extruder used, has barrel section, that are only 2 l/d long and at the extrusion conditions describe, i.e. rpm of between 400 rpm and 200 rpm allow barely the hear up of the starch water mix and are too low to obtain sufficient or substantial gelatinization of native starches , but in particular too low for high amylose starch which gelatinizes at temperatures substantially above 100 degree C, for example at 125 degree C. The patent WO discloses extrusion barrel temperatures that are not sufficiently high enough to substantially or completely gelatinize the starch as it is necessary for the purpose of this invention. Incomplete or not substantially cooked starch will not form a sufficiently continuous plastizised and homogeneous matrix , that is necessary for effective embedding or encapsulation. The temperatures and extrusion conditions however indicate , that because of relative low temperatures, that the viscosity of the mass inside the extruder causes the mechanical energy to be expressively high, as it is described, substantially higher than in those which are disclosed in the current invention. High shear is directly related to high specific mechanical energy , and this in turn increases the destructurization and dextrinization of starch , which in turn increases the solubility of extruded starch in aqueous systems. This fact is accepted in the art and numerously described in the scientific literature (Meuser et.al.). This ultimately decreases the stability of the product against moisture and subsequently diminishes the effect of a controlled release of the embedded substances. In addition, the encapsulant is undergoing the same high shear and high temperature, and might be affected and at least partially destroyed or it undergoes a decomposition into unknown solid or volatile substances.

The current invention however has the objective to carry out the encapsulation process specifically at low shear cooking conditions and by adding the encapsulant to the matrix after reducing the moisture and after reducing the temperature (in the above patent it is in all examples described that the encapsulant is exposed to high shear, and high temperatures). This minimize on one hand the amount of specific mechanical energy input into the starch based matrix. More importantly it protects the encapsulant against high temperature and /or high shear, that might otherwise lead to uncontrolled decomposition and might cause the generation and /or evaporation of unknown or harmful substances.

The cooling of the mass after cooking not described, but it is in the current invention disclosed to be also necessary to obtain sufficient density of pellets, that are not expanding.

The method of the current invention uses substantially higher temperatures in extrusion and higher moisture contents to substantially cook the starch and simultaneously to minimize the specific mechanical energy input to prevent substantial destructurization and dextrinization and to maximize the stability of the encapsulation matrix.

A key difference between the cited Patent WO and the current invention is that the method of the current invention adds the encapsulant after starch heating and cooking, and not before starch heating and cooking. This allows the addition of heat and / or shear sensitive components without affecting their thermal or mechanical destruction .

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Patent # US 3 786 125
Describes a method to produce encapsulated nutrients using extrusion temperatures of between 250 and 400 F and pressures of between 200 to 2500 psi and containing : High protein encapsulating agent, containing up to 40 % starch, gelatinizing starch and extruding it into an expanded product.

Main differences are: Process methodology, leads to different extrusion temperatures and SME(spec.mech.energy), the current invention uses addition of critical components after heat treatment and not before

Claims:

What is claimed is:

1. A method to encapsulate and/or embed components into a carbohydrate based matrix that comprises following steps:

- admixing of a starch containing solid and sufficient amount of water to substantially gelatinize the starch without substantially destructurizing and dextrinizing it
- heating the mix above the gelatinization temperature of the starch while conveying and mixing it inside an extruder
- maintaining at least 100 deg. C product temperature for sufficient time to substantially gelatinize the starch
- removal of some moisture of the cooked through either: an open extruder barrel section, or a vacuum dome/vent port or a combination of the above.
- reducing the temperature of the plastizised mass through moisture removal and/or additional barrel cooling
- conveying the gelatinized mass with reduced moisture and lower temperature towards a subsequent extruder barrel section, while maincaining sufficient temperature to admix the encapsulant without its mechanical or thermal destruction.
- adding one or more heatshear sensitive ingredients (pharmaceutical, nutritionally active, etc.) into one or more subsequent sections of the extruder, using either a solid feeder, also known as a side feeder, or, for liquid ingredients, using an injection nozzle and pumping the liquid at sufficient pressure into the plastizised mass.
- admixing the added ingredients using an appropriate low shear screw configuration, such as alternating small pitch conveying elements with distributive mixing elements for a total length of about 3-10 l/d to sufficiently admix and distribute and embed the added ingredients into the matrix.
- conveying the complete mix towards the extruder die while adjusting the product temperature for sufficient forming
- extruding through extrusion dies that have a diameter of between .5 and 3 mm into ropes with crossectional diameter of between .5 and 3 mm

2. A process according to claim 1 whereby the extruded ropes are being cut at the die using a rotating cutter, pellerizer or rotating knives

3. A process according to any of the previous claims whereby the extruded ropes are being cut away from die using appropriate cutting means into pellets that have a l/d ratio of between .5 and 10.

4. A process according to one or more of the previous claims whereby the extruded and cutted pellets are dried to sufficiently low moisture to ensure storage stability of the mix.

5. A process according to one or more of the previous claims whereby the extruded, cutted and at least partially dried pellets are being surface treated with filmbuilding substances to further encapsulate the extruded pellets.

6. A process according to one or more of the previous claims whereby the filmbuilding substances are either starch based, fat based using high melting fats, zein based, shellac based or chitosan based or a combination of the above and the filmbuilding substances may contain components that delay or prevent the access of light and / or oxygen to the matrix.

7. A process according to one or more of the previous claims whereby the filmbuilding substances can be applied using spray nozzles that are either located close to the extruder die or preferably after the drying means, when the moisture of the mass is at a level to ensure substantial storage stability, that is preferably less than 12%)

8. A process according to one or more of the previous claims whereby the filmbuilding substances can be applied using fluid bed applications, or conventional coating application

9. A method to encapsulate and/or embed components into a carbohydrate based matrix that comprises following steps:

- a) admixing of solids that contain substantial amount of pregelatinized starch and sufficient amount of water to substantially mix the blend without substantially degrading and dextrinizing the starch
- g) adding one or more heat/shear sensitive ingredients (pharmaceutical, nutritionally active, etc.) into the blend at sufficiently low temperature as to not destroying the encapsulant, using either a solid feeder, also known as a side feeder, or, for liquid ingredients , using an injection nozzle and pumping the liquid at sufficient pressure into the plastisized mass.
- h) admixing the added ingredients using appropriate screw configuration, such as alternating small pitch conveying elements with distributive mixing elements for a total length of about 3-6 l/d to sufficiently admix and distribute and embed the added ingredients into the matrix.
- l) conveying the complete mix towards the extruder die
- k) extruding through extrusion dies that have a diameter of between .5 and 3 mm into ropes with crossectional diameter of between .5 and 3 mm

10. A process according to claim 9 whereby the extruded ropes are being cut at the die using a rotating cutter, pelletizer or rotating knives

11. A process according to claim 9 and 10 whereby the extruded ropes are being cut at the die using a rotating cutter, pelletizer or rotating knives

12. A process according to claim 9-11 whereby the extruded ropes are being cut away from die using appropriate cutting means into pellets that have a l/d ratio of between .5 and 10.

13. A process according claim 9-12 whereby the extruded and cutted pellets are dried to sufficiently low moisture to ensure storage stability and stability of the glassy matrix.

14. A process according to any of the previous claims whereby the forming step is performed using a single screw extruder.

15. A process according to claim 9 -13 whereby the extruded, cutted and at least partially dried pellets are being surface treated with filmbuilding substances to further encapsulate the extruded pellets.

16. A matrix composition that is treated according to one or more of the previous claims and that comprises at least one starch from plant sources, i.e. from potato, tapioca, wheat, corn, rice or other starch delivering plants.

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17. A matrix composition that is treated according to one or more of the previous claims and that comprises N-vinylpyrrolid-2-one

18. A matrix composition that is treated according to one or more of the previous claims and that comprises hydrophobic substances such as oil and fats with melting points up to above 60 degree C

19. A matrix composition that is treated according to one or more of the previous claims and that comprises dextrins

20. A matrix composition that is treated according to one or more of the previous claims and that comprises pregelatinized starches

21. A matrix composition that is treated according to one or more of the previous claims and that comprises flours from wheat, corn, rice, barley, oat, rye, potato, tapioka, pea

22. A matrix composition that is treated according to one or more of the previous claims and that comprises light protection agents such as for example cocoa based or titaniumdioxide

23. A matrix composition that is treated according to one or more of the previous claims and that comprises at least one starch with a amylose content of above 25 %.

24. A matrix composition that is treated according to one or more of the previous claims and that comprises soluble fiber

25. A matrix composition that is treated according to one or more of the previous claims and that comprises pectins

26. A product that is made by the process according to one or more of the revious claims that contains encapsulants that are either pharmaceutically, neutraceutically, nutritionally or biologically active components

27. A product that is made by the process according to one or more of the previous claims that contains one or more encapsulants from the following group: acetaminophen, acetohexamide, acetyldigoxin, acetylsalicylic acid, acromycin, amipamil, benzocaine, beta-carotene, chloramphenicol, chlordiazepoxide, chlormadinone acetate, chlorothiazide, cinnarizine, clonazepam, codeine, dexamethasone, diazepam, dicoumarol, digitoxin, digoxin, dihydroergotamine, drotaverine, flunitrazepam, furosemide, gramicidin, griseofulvin, hexobarbital, hydrofluormethiazide, indomethacin, ketoprofen, lonetil, medazepam, mefruside, methandrostenolon e, methylprednisolone, methylsulfadiazine, nalidixic acid, nifedipine, nitrazepam, nitrofurantoin, nystatin, estradiol, papaverine, phenacetin, pheno-barbital, phenylbutazone, phenytoin, prednisone, reserpine, spironolactone, streptomycin, sulfamethazine, sulfamethizole, sulfamethoxazole, sulfamethoxydiazine, sulfaperin, sulfathiazole, sulfisoxazole, testosterone, tolazamide, tolbutamide, trimethoprim, thyrothricin.bethamethasone, thiotic acid, sotalol, salbutamol, norfenefrine, silymarin, dihuroergotamine, buflomedil, etofibrate, indometacin, oxazepam, beta acetyl digoxin, piroxicam, haloperidol, ISMN, amitriptylin, diclofenac, nifedipine, verapamil, pyritinol, nitrendipin, doxycycline, bromhexine, methylprdnisolone, clonidine, fenofibrate, allopurinol, pirenzepine, levothyroxin, tamoxifen, metildigoxin, o-(beta-hydroxyethyl)-rutoside, propicillin, aciclovir mononitrate, paracetamol, naftidrofuryl, pentoxifylline, propafenone, acebutolol, L-thyroxin, tramadol, bromocriptine, loperamide, ketotifen, fenoterol, cadobelisate, propanolol, enalaprilhydrogen maleate, bezafebrate, ISDN, gallopamil, xantinol nicotinate, digitoxin, flunitrazepam, bencyclane, dexapanthenol, pindolol, lorazepam, diltiazem, piracetam, phenoxymethylpenicillin, furosemide, bromazepam, flunarizin, erythromycin, metoclopramide, acemetacin, ranitidin, biperiden, metamizole, doxepin, dipotassium chlorazepate, tetrazepam, estramustine phosphat, terbutaline, captopril, maprotiline, prazosin, atenolol, glibenclamide, cefaclor, etilfrine, cimetidine, theophylline, hydromorphone, ibuprofen, primidone, clobazam, oxaceprol, medroxyprogesterone, flecainid, pyridoxal 5 phosphat glutaminate, hymechromone, etofylline clofibrate, vincamine, cinnarizine, diazepam, ketoprofen, flupentixol, molsimine, glibornuride, dimetinden, melperone, soquinolol, dihydrocodeine, clomethiazole, clemastine, glisoxepide, kallidinogenase, oxyfedrine, baclofen, carboxymethylcysteine, thioridazine, betahistine, L-tryptophan, muriol, bromelaine, prenylamine, salazosulfapyridine, astemizol, sulpiride, benzerazide, dibenzepine, acetylsalicylic acid, miconazol, nystatin, ketoconazole, sodium

picosulfate, colcytamine, gemfibrocil, rifampicin, fluocortolone, mexiletin, amoxicillin, terfenadrin, mucopolysaccharide polysulfade, triazolam, mianserin, tiaprofenic acid, amezinium metilsulfate, mefloquine, probucol, quinidine, carbamazepine, L-aspartate, penbutolol, piretanide, aescin amitriptyline, cyproterone, Sodium valproinate, mebeverine, bisacodyl, 5-aminosalicylic acid, dihydralazine, magaldrate, phenprocoumon, amantadine, naproxen, carteolol, famotidine, methyldopa, auranofine, estriol, nadolol, levomepromazine, doxorubicin, medofenoxate, azathioprine, flutamide, norfloxacin, fendiline, prajmalium bitartrate. Nutraceutical components, such as antioxidants, phytochemicals, hormons, vitamins, minerals, microorganisms, prebiotics, probiotics, trace elements, essential and/or highly unsaturated fatty acids.

28. Products that are produced using the method described in one or more of the previous claims

29. Application of the products that are being produced using the method described in one or more of the previous claims to humans and animals

30. Application of the products that are being produced using the method described in one or more of the previous claims in the field of agriculture to control the release of active substances, such as herbicides, pesticides, insecticides or other substances that are advantageously embedded or encapsulated to control or delay the release from their surrounding matrix.

Description of the Figures

Figure 1:

The figure shows a simplified schematic representation of the process of the invention. A preblend that contains at least one starch and water may be preconditioned at room temperatures or elevated temperatures and thereafter fed into an extruder. Twin screw extruder are preferred, since they provide superior mixing action. It is possible to perform the forming step using a single screw extruder. After the matrix has been cooked, evaporated, and mixed with the encapsulant, the product is being extruded through dies, and is being cut either at the die face or away from the die using a separate cutting means. After cutting, the product is being dried and may be optionally coated in conventionally coating equipment.

Figure 2:

Figure 2 shows schematically an overview of the extrusion process of this invention. A preblend of starches with other components may be prepared and stored or conditioned prior to feeding it into an extruder.

The dry blend is normally fed gravimetrically or volumetrically into the feeding section of an extruder in barrel 1. Temperatures are normally about room temperature and can vary from about 0 to about 85 degree Celsius. Higher temperatures cause steam to escape in the feed port. The barrel (1) is cooled with water to maintain a temperature between about 10 and 50 degree Celsius. Screw elements with large pitch convey the dry blend into barrel 2. Decreasing pitch increases the degree of fill in the barrel and offset forward pitch elements cause distributive mixing of the added liquid with the dry blend. Simultaneously the temperature of barrel 2 is at a level of about between 60 and 120 degree C to heat the wet blend, that is conveyed using medium pitch screw elements into barrel 3. Barrel temperature in barrel 3 is between about 110 and 180 degree C , preferably between about 120 and 160 degree C. The temperature of the mix increases at a rate that is mainly affected by the contact time of the material and the barrel and exchange of material by the screws. The contact time is a function of rpm and throughput rate, which determine the degree of fill; the material exchange is affected by the screw configuration. In barrel 3, mixing elements are alternating with medium pitch conveying elements and ensure sufficient material exchange and high degree of fill. Staggering all elements in this section with an angle of about 90 degrees to each other allows additional leakage flow and prevents high shear. The mass is forming a dough, that has a temperature of about 5 to 30 degrees lower than the barrel temperature, in this case 90 to 155 degree C. The gelatinization of starch starts to occur. Optional steam injection may be applied in this section to increase the thermal energy input and further decrease the mechanical energy input. Low pitch conveying, alternating with short reverse pitch staggered elements in barrel 4 and 5 at barrel temperatures of about 110 to more than 200, for example 220 degree C result in higher degree of fill, low shear distributive mixing and further heating and cooking of the

mass. which reduces its viscosity and thus the shear into the mass. At the beginning of barrel 6, immediately before the vent opening . is a non staggered reverse pitch conveying element located, that increases the degree of fill and increases pressure of the mass in barrel 5 and the beginning of barrel 6. This pressure is needed to complete the cook of the starch . and in case the starch is high in amylose, temperatures of about 120 degrees C can be reached under this pressure, which is between about 5 and 30 bars. for example 10 bars. After the non staggered reverse pitch element, a high pitch conveying element follows, that decreases the degree of fill by its function of higher conveying capacity. One or more open barrel sections , optionally connected to a vacuum pump allow the pressure to decrease substantially, for example from about 10 bar to about less than 1 bar. This pressure drop results in water evaporation and subsequent moisture loss of the cooked mass. The amount of moisture lost in the vacuum sections depends upon residence time of product in this section, which depends upon rpm of the screw. and pitch of the screw elements: and available open area for water evaporation, that can vary between one or two or more vent ports. Moisture loss also depends upon the barrel temperatures in barrel 6 and 7. High temperatures above for example 150 degree force more steam to escape than low barrel temperatures. for example 80 degree C. Temperatures in this example can be between about 80 and 160, preferably about 100 to 120 degree C. at the end of barrel 7 the product temperatures are around 100 degree C. The subsequent barrel 8 is being cooled down to reduce mass temperature further. Temperatures in this section can be between about 20 and 90 degree C. Low pitch conveying elements increase degree of fill to enhance heat transfer from product to barrel.

Low rpm are critical for optimum processing. Ranges are between about 20 and about 200 rpm . Higher rpm introduce more shear, dextrinize and destructurize more starch. reduce capability or water removal . reduce heat transfer capability, i.e. heating and cooling. The lower limit of rpm is primarily throughput i.e. economically limited.

Barrel 9 is equipped with an horizontally orientated side feeder, that introduces solid encapsulant. Optionally liquid encapsulant can be introduced into the blend via injection nozzle at the same vicinity of this location. The side feeder is designed as a twin screw feeder, known to anyone skilled in the art. The temperature of the barrel is dependent upon the heat sensitivity of the encapsulant and can for example be adjusted to temperatures between about 20 and 90 degree C. In case the encapsulant is oxygen sensitive, the hopper of the side feeder can be optionally flooded with CO2 or nitrogen. After the mix has been introduced into the barrel section. screw elements with forward pitch and staggered position mix the added ingredients into the matrix while minimizing the introduction of shear energy. Simultaneously, the temperature of the barrels are being adjusted to maintain low enough as to not thermally destroy the encapsulant and to ensure that viscous properties of dough are sufficiently high to allow extrusion and forming of ropes that can be cut into pellets. Temperatures may range between 25 and 95 degree C. preferably around 60 to 80 degree C.

After exiting the barrel section 10 of the extruder. the mass enter into the die area, where it is being distributed into a multitude of openings. Critical is the rate per die area , which should be less than 5 kg/h per mm^2 . preferably less than 3 kg/h per mm^2 and most preferably less than 2 kg/h per mm^2.

Figure 3:

Figure 3 is an alternative way to exercise the current invention. The cooking process , screw configuration and temperature profile is similar than described in fig. 2 . The differences are , that the cooking is accomplished with one less extruder barrel section. the venting is accomplished with one less barrel section and the mixing of the encapsulant is accomplished using more mixing screw configuration in the last two barrels of the extruder. This configuration can be chosen, when the material that is to be encapsulated is less heat and shear sensitive and /or needs more distributive mixing and /or the starch can be reduced in moisture using only one vent port.

Figure 4:

Fig. 4 shows an execution of the invention , whereby the starch is pregelatinized and can be mixed with the encapsulant using a shortened twin screw extruder. In this case, the moisture and the temperature need to be sufficient as to provide sufficiently low viscosity as to not to destructurize or dextrinize the pregelatinized starch. For example, the added moisture content might be between about 20 and 45% , preferably between about 25 and 35 % , for example about 30 %. The temperature of barrel one is kept at about room

temperature, but barrel 2 needs to be about between 50 and 100 degree C to maintain low viscosity and low specific mechanical energy input. The product might be cooled at the end of the extruder the same way than it was described for figure 2.

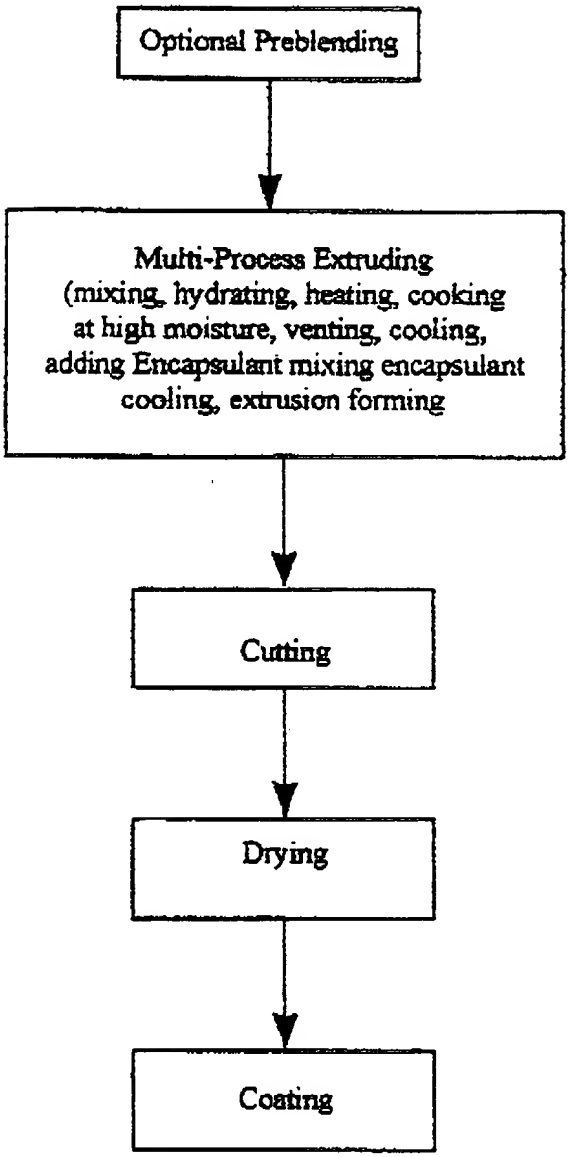

Fig. 1:

Schematical Representation of the Method

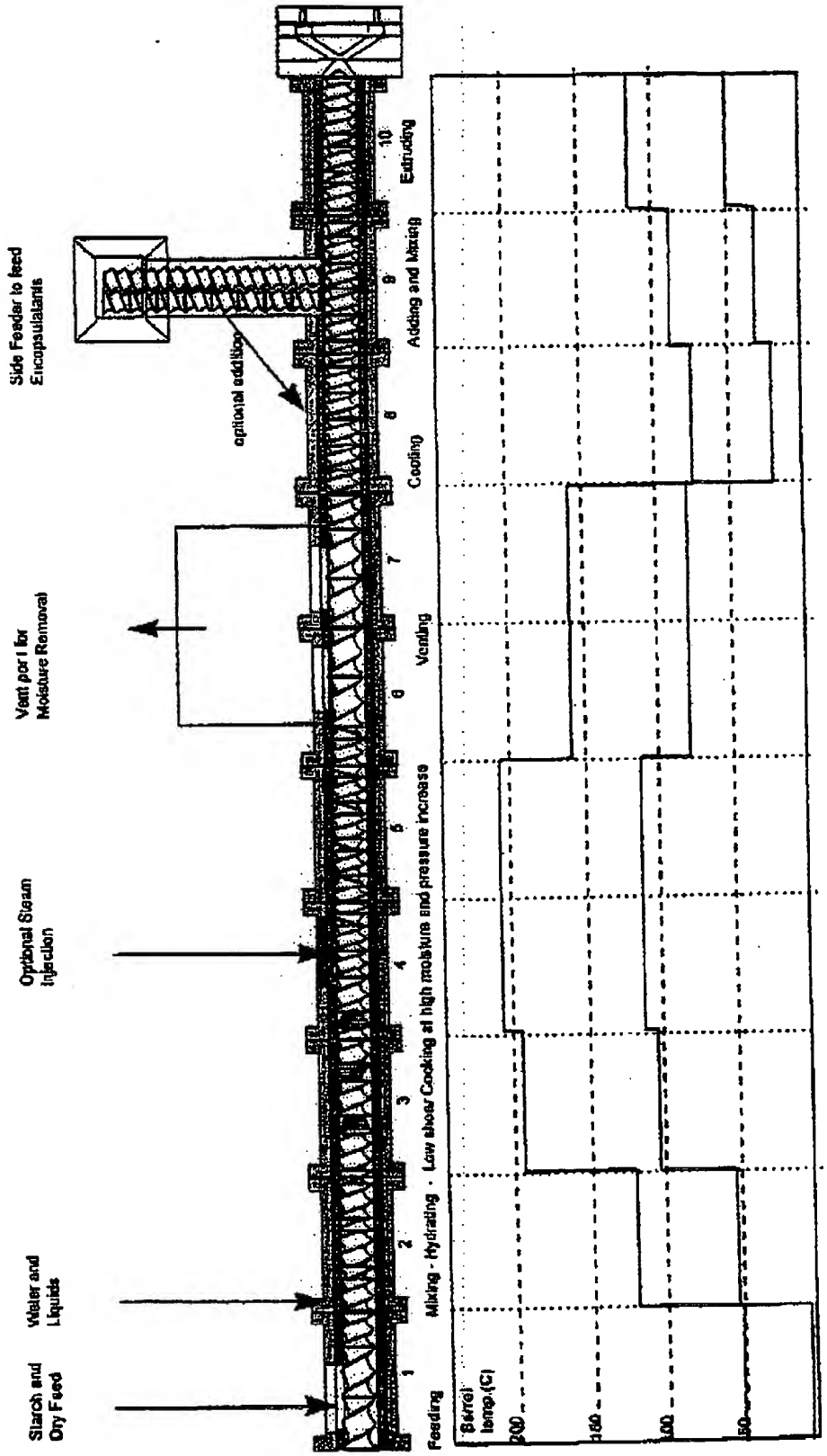

Figure 2

10/27/96 B.van Lengerich: Method for the encapsulation and embedding of components

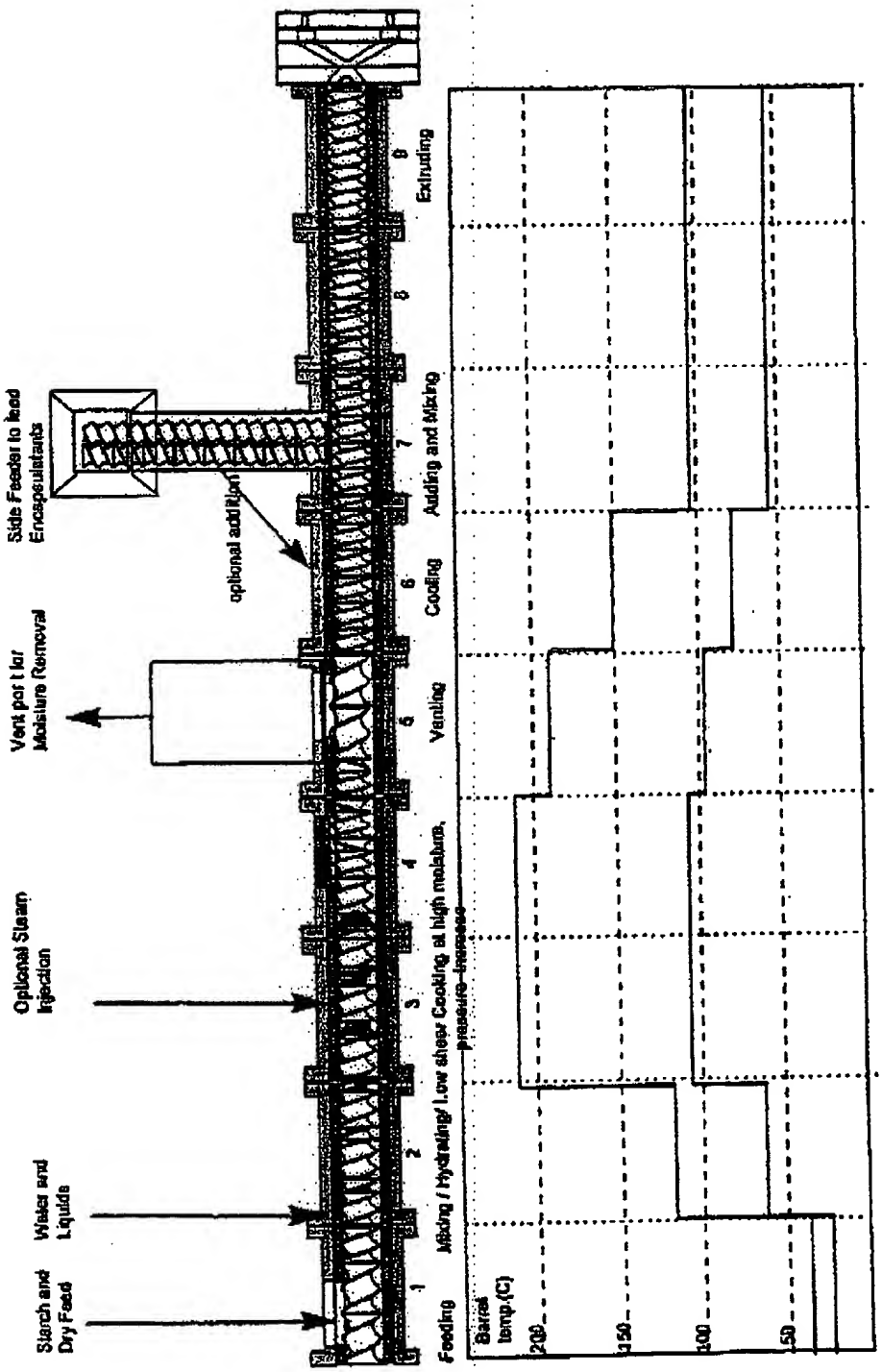

Figure 1

10/27/96 13.van Lengerich: Method for the embedding and encapsulation of components

Figure 4